



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

70

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/523,629

03/21/2005

Steven Brian Gendreau

EX03-058C-US

1872

63572 7590 05/14/2007  
MCDONNELL BOEHNEN HULBERT @ BERGHOFF LLP  
300 SOUTH WACKER DRIVE  
SUITE 3100  
CHICAGO, IL 60606

EXAMINER
----------

DUFFY, BRADLEY

ART UNIT	PAPER NUMBER
----------	--------------

1643

MAIL DATE	DELIVERY MODE
-----------	---------------

05/14/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/523,629	GENDREAU ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Brad Duffy	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 04 February 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-25 are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

1. Claims 1-25 are pending in this application and are currently subject to restriction.

#### ***Election/Restrictions***

2. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim 5, drawn to a method for identifying a candidate AXIN pathway modulating agent comprising a kinase assay.

Group II, claim 6, insofar as the claim is drawn to a method for identifying a candidate AXIN pathway modulating agent comprising an apoptosis assay.

Group III, claim 6, insofar as the claim is drawn to a method for identifying a candidate AXIN pathway modulating agent comprising a cell proliferation assay.

Group IV, claim 6, insofar as the claim is drawn to a method for identifying a candidate AXIN pathway modulating agent comprising an angiogenesis assay.

Group V, claim 6, insofar as the claim is drawn to a method for identifying a candidate AXIN pathway modulating agent comprising an hypoxic induction assay.

Group VI, claims 13-15 and 20-22, insofar as the claims are drawn to a method for modulating an AXIN pathway of a cell comprising contacting a cell with an antibody that specifically binds to a PAPSS polypeptide.

Group VII, claims 13-15 and 20-22, insofar as the claims are drawn to a method for modulating an AXIN pathway of a cell comprising contacting a cell with a small molecule that specifically binds to a PAPSS polypeptide.

Group VIII, claim 20-22, insofar as the claims are drawn to a method of modulating an AXIN pathway a cell comprising contacting a cell with a nucleic acid modulator that specifically binds to a PAPSS nucleic acid.

Group IX, claim 23-25, insofar as the claims are drawn to a method for determining the likelihood of disease comprising determining the expression of a gene encoding PAPSS.

3. Claims 1-4, 7-12, and 16-19 are linking claims, linking the inventions of Groups I-V. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s). Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim depending from or otherwise including all the limitations of the allowable linking claims will be entitled to examination in the instant application. Applicants are advised that if any such claims depending from or including all the limitations of the allowable linking claims are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

4. The inventions listed as Groups I-IX do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

To have a general inventive concept under PCT Rule 13.1, the inventions need to be linked by a special technical feature. The technical feature recited in claim 1 is a method comprising the steps of providing (a) providing an assay system comprising a PAPSS polypeptide or nucleic acid; (b) contacting the assay system with a test agent under conditions whereby, but for the presence of the test agent, the system provides a reference activity; and (c) detecting a test agent-biased activity of the assay system, wherein a difference between the test agent-biased activity and the reference activity identifies the test agent as a candidate AXIN pathway modulating agent. This claim lacks inventive step over Deyrup et al (JBC, 274(41):28929-28936, 1999). Deyrup et al teach an assay system comprising a PAPSS polypeptide, wherein the assay system is contacted with DEP or phenylglyoxal test agents and a decrease in the residual kinase and sulfurylase activity present in the PAPSS polypeptide is detected compared to its reference activity (see entire document, e.g., page 28931, left column and Fig 1). Therefore, since Deyrup et al teach a difference between the test agent-biased activity and the reference activity in this assay system, DEP and phenylglyoxal are inherently identified as candidate AXIN pathway modulating agents. Since Deyrup et al teach the technical feature recited in claim 1, it is not a special technical feature and the groups do not relate to a single general inventive concept as required under PCT Rule 13.1.

For these reasons, the special technical feature of the invention of Group I is a method for identifying a candidate AXIN pathway modulating agent comprising a kinase assay.

The special technical feature of the invention of Group II is a method for identifying a candidate AXIN pathway modulating agent comprising an apoptosis assay.

The special technical feature of the invention of Group III is a method for identifying a candidate AXIN pathway modulating agent comprising a cell proliferation assay.

The special technical feature of the invention of Group IV is a method for identifying a candidate AXIN pathway modulating agent comprising an angiogenesis assay.

The special technical feature of the invention of Group V is a method for identifying a candidate AXIN pathway modulating agent comprising an hypoxic induction assay.

The special technical feature of the invention of Group VI is a method for modulating an AXIN pathway of a cell comprising contacting a cell with an antibody that specifically binds to a PAPSS polypeptide.

The special technical feature of the invention of Group VII is a method for modulating an AXIN pathway of a cell comprising contacting a cell with a small molecule that specifically binds to a PAPSS polypeptide.

The special technical feature of the invention of Group VIII is a method of modulating an AXIN pathway a cell comprising contacting a cell with a nucleic acid modulator that specifically binds to a PAPSS nucleic acid.

The special technical feature of the invention of Group IX is a method for determining the likelihood of disease comprising determining the expression of a gene encoding PAPSS.

Accordingly the groups are not so linked as to form a single general concept under PCT Rule 13.1.

5. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not

patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103 (a) of the other invention.

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(l).

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brad Duffy whose telephone number is (571) 272-9935. The examiner can normally be reached at Monday through Friday from 7:00 AM to 4:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, can be reached at (571) 272-0832. The official fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Respectfully,  
Brad Duffy  
571-272-9935

bd  
May 1, 2007

  
STEPHEN L. RAWLINGS, PH.D.  
PRIMARY EXAMINER